

RADIOMETER AMERICA INC.

K961354

Exhibit VII

MEDICAL DIVISION

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JUN 14 1996

SUBJECT: 510(k) SUMMARY

FROM: Donald L. Baker
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Radiometer America, Inc.
810 Sharon Drive
Westlake, Ohio 44145
(216)871-8900, Ext287 or 1-800-736-0600
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DATE: April 1, 1996

PRODUCT: Trade Name - Qualicheck™4 Metabolite
Common Name - Quality Control
Classification Name - Controls for Blood Gas (assayed and unassayed)

PREDICATE

DEVICE: Qualicheck 4 Glucose

PRODUCT

DESCRIPTION: Qualicheck 4 Metabolite is a four level quality control system consisting of part numbers S3630, S3640, S3650, and S3660. Each level consists of 30 ampoules per box, 2 mL solution per ampoule.

INTENDED

USE: Qualicheck 4 Metabolite is intended for checking the precision and accuracy of Radiometer and non-Radiometer analyzers for pH/Blood Gases, Electrolytes, Glucose and Lactate.

TECHNOLOGICAL CHARACTERISTICS

VERSUS PREDICATE

DEVICE: Qualicheck 4 Metabolite is technologically similar to Qualicheck 4 Glucose.

SUBSTANTIAL

EQUIVALENCE: Qualicheck 4 Metabolite is substantially equivalent in features and characteristics to the current Qualicheck 4 Glucose (K952637) marketed by RadiometerAmerica Inc. The only difference is the addition of the lactate analyte.